

REMARKS

Status of Claims

Claims 1-11 were pending in this application. Claims 1-6, 9 and 10 are withdrawn. Upon entry of the present Amendment, claims 7, 8 and 11 are presented for examination.

Claims Objections

Claims 8 and 11 were objected to for being dependent on withdrawn claims. Applicants have amended claims 8 and 11 to depend from independent claim 7. Withdrawal of the objections is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 7, 8 and 11 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Specifically, on page 2 of the Office Action it states that it is not clear what subject matter the term “recovery doubling time” intends to point out. Applicants respectfully submit that “recovery doubling time” is clearly described beginning on page 12, line 20 of the originally filed application. In particular, it provides that subsequent to cell expansion procedures, cell bank stability is determined by two parameters, one being cell recovery doubling time. To determine cell recovery doubling time the cells are harvested from flasks and are counted when close to confluence and also the following day. The values obtained are compiled and graphed in FIGS. 2 and 3 comparing various recovery doubling times.

Further on page 2, the Office Action states that the phrase “after one year” does not clearly point out the starting point of the “one year”. Applicants have amended claim 7 to clarify that the starting point is “after one year of freezing.” Claims 8 and 11 now depend from independent claim 7.

On page 3 of the Office Action it states that the term “stable” is a relative term that is not defined by the claims or specification. Applicants respectfully disagree. Specifically, on page 4,

beginning on line 8 of the originally filed application, it states that the process of the present invention ensures “a long-term supply of standardized cells” providing a stable substrate which allow for “consistent production”. Further, on page 6, beginning on line 27, it is described that the present invention provides a “standardized and consistent” way to generate reliable and stable cell banks for viral vaccines productions.

For these reasons, Applicants respectfully submit that claims 7, 8 and 11 satisfy the requirements under § 112, second paragraph, and respectfully request that the rejections be withdrawn.

Claim Rejections Under 35 U.S.C § 102(b) and § 103(a)

Claims 7, 8 and 11 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by or in the alternative, under 35 U.S.C. § 103(a) as obvious over Price et al. (US Patent No. 6,103,529), Frazzati-Gallina et al. (2001, J. Biotech) or Kistner et al. (WO 96/15231). Applicants respectfully traverse these rejections.

The Office Action cited Price et al. for teaching Vero cells grown in serum-free medium comprising a rice hydrolysate, Frazzati-Gallina et al. for teaching Vero cells cultured in virus production-serum free medium (VP-SFM) and Kistner et al. for teaching a protein-free Vero cell bank. Independent claim 7 now provides for a stable serum-free Vero cell bank having a cell viability of at least 80% and a recovery doubling time between 40 and 60 hours after one year of freezing, wherein the cell bank comprises (a) an enzymatic hydrolysate cryostabilizer and (b) dimethylsulfoxide (DMSO). The use of DMSO prevents ice crystals from forming and destroying the cell membrane which can lead to cell death.

Price et al., Frazzati-Gallina et al. and Kistner et al. fail to disclose a stable serum-free Vero cell bank having a cell viability of at least 80% and a recovery doubling time between 40 and 60 hours after one year of freezing, wherein the cell bank comprises (a) an enzymatic hydrolysate cryostabilizer and (b) dimethylsulfoxide (DMSO), as provided in claim 7. Because the cited references do not disclose each and every limitation of claim 7, a *prima facie* case of

anticipation has not been established. Claims 8 and 11, which depend from claim 7, are also not anticipated by the cited references. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Further, a *prima facie* case of obviousness has not been established since Price et al., Frazzati-Gallina et al. and Kistner et al. fail to teach or suggest a stable serum-free Vero cell bank having a cell viability of at least 80% and a recovery doubling time between 40 and 60 hours after one year of freezing, wherein the cell bank comprises (a) an enzymatic hydrolysate cryostabilizer and (b) dimethylsulfoxide (DMSO), as provided in claim 7. Even combining each of the cited references fails to teach or suggest all the limitations of claim 7. Claims 8 and 11, which depend from claim 7, are also not obvious over the cited references. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

In view of the foregoing discussion, Applicants submit that the present application is in condition for allowance. Reconsideration and allowance are respectfully requested.

If a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at (845) 602-4760. Should the Commissioner determine that any other fee(s) is due or that any credit for overpayment is required, the Commissioner is hereby authorized to charge any additional fee(s) and/or credit any overpayments to Deposit Account No. 16-445.

Respectfully submitted,

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/Carol A. McKeever/
Carol A. McKeever
Attorney for Applicants
Registration No. 60,669

Pfizer
Patent Law Department
Five Giralta Farms
Madison, NJ 07940
Tel. No. (845) 602-4760